Complete Summary

GUIDELINE TITLE

Dabigatran etexilate for the prevention of venous thromboembolism after hip or knee replacement surgery in adults.

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Dabigatran etexilate for the prevention of venous thromboembolism after hip or knee replacement surgery in adults. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Sep. 26 p. (Technology appraisal guidance; no. 157).

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Venous thromboembolism after hip or knee replacement surgery

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Prevention

CLINICAL SPECIALTY

Hematology
Internal Medicine

Orthopedic Surgery
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To evaluate the clinical effectiveness and cost-effectiveness of dabigatran etexilate for the prevention of venous thromboembolism after hip or knee replacement surgery

TARGET POPULATION

Adults undergoing hip or knee replacement surgery

INTERVENTIONS AND PRACTICES CONSIDERED

Dabigatran etexilate (Pradaxa)

MAJOR OUTCOMES CONSIDERED

- Clinical effectiveness
  - Mortality
  - Incidence of deep vein thrombosis (DVT)
  - Incidence of pulmonary embolism (PE)
  - Adverse events including bleeding events
  - Post DVT complications, including post-thrombotic syndrome
  - Length of hospital stay
  - Health-related quality of life
- Cost-effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform an assessment of the manufacturer's submission on the technology considered in this appraisal and prepare an Evidence Review Group (ERG) report. The assessment report for this technology appraisal was prepared

by the School of Health and Related Research (ScHARR), University of Sheffield (see the "Availability of Companion Documents" field).

Critique of Manufacturer's Approach

Description of Manufacturer's Search Strategy and Comment on whether the Search Strategy Was Appropriate

The searches undertaken by the manufacturer to identify all relevant randomised controlled trials (RCTs) were conducted in February 2008. The search strategy utilises terms to identify the patient group (hip and knee replacement surgery), the intervention (dabigatran etexilate) and the type of evidence (study, trial). No language restrictions appear to have been applied. The strategy is simple and reasonably effective, but a form of methodological filter is applied (study.mp or trial.mp), even though it is clearly stated that the strategy was intended not to identify a particular study design. The filter used is not validated nor is its efficacy reported elsewhere, and given the small number of citations retrieved, these terms could have been omitted, without greatly increasing the work involved. The resulting strategy would have been more sensitive and less vulnerable to criticism.

Only five databases were searched (Medline, Medline in-process, Embase, The Cochrane Library and the manufacturer's own in-house database, BILIT/pre-BILIT); key data may therefore have been missed, particularly regarding unpublished data (no research registers, such as the National Research Register or Current Controlled Trials, were searched, other than the manufacturer's own in-house database). Key databases overlooked include the Science Citation Index (Web of Science) and BIOSIS. The searches also applied date limits, which were not justified in the manufacturer's submission (MS). The range reported to be searched for Medline in-process (1996-2008) is not congruent with the scope of the database.

No methods, other than the searching of the above electronic databases, were used to identify studies (e.g., handsearching of journals, reference and citation tracking). The use of such supplementary methods is required by the QUORUM checklist (Moher, 1999). The MS fails to report the use of such methods, or to explain why these methods were not used.

Statement of the Inclusion/Exclusion Criteria Used in the Study Selection and Comment on whether They Were Appropriate

<u>Inclusion Criteria</u>

- Randomised controlled trials (RCTs) evaluating dabigatran etexilate (DBG) in the prevention of thromboembolic events after total hip or knee replacement
- Observational studies evaluating DBG in the prevention of thromboembolic events after total hip or knee replace

<u>Exclusion Criteria</u>

- Reviews

- Comments letters/editorials containing no original data
- Abstracts presenting results of studies subsequently published in full
- Studies not using the dose of DBG proposed for use in the UK for this indication
- Studies which did not have clinical efficacy/safety as the primary objective

The inclusion/exclusion criteria appear to be appropriate, but the rationale behind the stated inclusion and exclusion criteria was not given.

What Studies Were Included in the Submission and What Were Excluded?

Of the 19 citations identified by the search of electronic databases, 16 were correctly excluded for the following reasons:

- RCT with inappropriate dose of DBG (1)
- Comment letters/editorials/reviews with no original data (3)
- Non-RCTs with clinical data potentially relevant to the decision problem (0)
- Non-RCTs without clinical data (e.g., pharmacokinetic or dose-ranging studies) (5)
- Abstracts of conference presentations of trial results subsequently published in full (7)

The remaining three studies were included. Details of the study design and patient characteristics of the included studies are summarised in Table 4 of the ERG report (see the "Availability of Companion Documents" field).

Refer to Section 4.1 of the ERG report (see the "Availability of Companion Documents" field) for additional information on search strategies.

NUMBER OF SOURCE DOCUMENTS

Clinical Effectiveness

Three randomized controlled trials (RE-NOVATE, RE-MODEL and RE-MOBILIZE) were included.

Cost-Effectiveness

Three above-mentioned studies and a manufacturer's model were submitted.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform an assessment of the manufacturer's submission on the technology considered in this appraisal and prepare an Evidence Review Group (ERG) report. The assessment report for this technology appraisal was prepared by the School of Health and Related Research (ScHARR), University of Sheffield (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Description and Critique of Manufacturers Approach to Validity Assessment

A completed table recording decisions regarding trial quality assessment was not in the manufacturer's submission (MS). A completed validity assessment form for the three trials, provided at the request of the ERG, is reproduced in Table 5 of the ERG report (see the "Availability of Companion Documents" field).

The critical appraisal of the trials conducted in the MS is based on the full details of the trials, as reported in the MS, rather than the published details. For example, data about efforts to protect blinding (e.g., database lock) were not reported in the published papers. There are also three issues with the submitted critical appraisal.

Firstly, Table 5 in the ERG report (see the "Availability of Companion Documents" field) states that each patient received "twice daily subcutaneous injections", but the published papers of the RE-NOVATE and RE-MODEL trials state that only a single daily subcutaneous injection was given. Secondly, the dosing regimens described for the RE-NOVATE and RE-MODEL trials are not reported accurately. Finally, the MS reports on efforts to ensure blinding, but does not report if any of these studies assessed the success of blinding, as required by point 11 on the CONSORT checklist (http://www.consort-statement.org/). The assessment of the ERG is that they did not.

The validity assessment tool used in the MS is not referenced and the questions are not entirely adequate. The trials included were all non-inferiority trials, and an appropriate validity assessment tool is available for assessing the quality of such trials (see Table 6 of the ERG report [see the "Availability of Companion Documents" field]). The tool used in the MS appears to be appropriate for assessing superiority trials only.

The results of the validity assessment of the ERG are reported in Table 7 of the ERG report (see the "Availability of Companion Documents" field).

The overall methodological quality of the included trials was good, but a more appropriate validity assessment tool was available and could have been used in the MS. The relevant extension of the CONSORT statement regarding the reporting of non-inferiority trials was available both at the time of the publication of the RE-NOVATE and RE-MODEL trials and for validity assessment of the trials included in the MS.

Describe and Critique the Statistical Approach Used

The MS contained a series of meta-analyses. It reported relative risks (RR) for fixed effects models of the 2 pivotal trials combined (RE-NOVATE and RE-MOBILIZE) and all three trials combined, and a random effects model for all three trials combined. At the request of the ERG, the manufacturer also provided:

- A random effects model meta-analysis of the 2 pivotal trials combined
- Risk differences (RD; absolute risk reductions) in both fixed and random effects models for the two pivotal trials, and all three trials combined
- Fixed and random effects models for both RR and RD for the two total knee replacement (TKR) trials combined (RE-MODEL and RE-MOBILIZE)

A pooled analysis of RD for the two pivotal trials was reported in the MS. The rationale for presenting and pooling individual patient data was not reported. The analyses themselves appear to have been reproduced from a source external to the MS and were only performed on the secondary efficacy outcome (no explanation for this was given). The statistical methods of pooling were not made explicit in the MS.

Sensitivity analyses presenting best and worst case scenarios were also performed, imputing no events for missing trial data, or an event for each piece of missing data, respectively, as well as a pooled analysis of all three trials using a fixed effects model only. The rationale for pooling the 3 trials in this way, with a fixed effects model only, was not given.

The ERG also notes that the pooling of data is viewed as inadequate for the assessment of efficacy. A pooled analysis focuses on treatment groups rather than on studies, ignores validity of the comparisons and is subject to bias termed 'Simpson's paradox' in probability. A more satisfactory statistical technique for combining the results from two or more separate studies is meta-analysis. All efficacy and safety meta-analyses requested by the ERG were provided by the manufacturer.

Summary Statement

The manufacturer's search strategy was adequately reported but limited, although the submission appears to contain all of the relevant head-head RCTs. Processes and validation of study screening and data extraction were not reported in full, and the validity assessment tool used was not entirely appropriate or adequate, although the application of a more appropriate tool did not greatly alter judgments on the overall quality of the included trials. The outcomes selected were relevant and appropriate. Statistical methods were explicitly described for the meta-analyses and all required meta-analyses were performed. Pooled

analyses were also reported, although they were not described fully and may be inappropriate.

Refer to Section 4 of the ERG report (see the "Availability of Companion Documents" field) for more information on methods used to analyze the evidence.

Economic Evaluation

Model Validation

The MS describes internal pre-specified quality control checks of all input data and programming and external validation by a panel of clinical experts.

The ERG are not aware of any further trials or models against which the manufacturer's model could be validated.

Critique of Approach Used

The decision tree/state transition model which the manufacturer used is considered to be appropriate for the economic analysis.

Refer to Section 5 of the ERG report (see the "Availability of Companion Documents" field) for more information on economic evaluation.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The manufacturer submitted an economic model assessing the impact of dabigatran etexilate for venous thromboembolic events (VTE) prevention after hip and knee replacement compared with low molecular weight heparin (LMWH) and fondaparinux. The model included an acute-phase decision-tree model to 10 weeks after surgery and a chronic-phase Markov model with a lifetime (60-year) time horizon.

Key assumptions in the economic evaluation are detailed in the manufacturer's submission. Among these, the manufacturer assumed that all LMWHs are bioequivalent, because literature on dalteparin, tinzaparin and enoxaparin and the national Institute for Health and Clinical Excellence (NICE) clinical guideline 'Venous thromboembolism' (NICE clinical guideline 46) recommendations did not distinguish between LMWHs. Furthermore, a zero cost for administration was assumed for dabigatran etexilate, whereas LMWH and fondaparinux were

assumed to require resources for administration (including provision for a proportion of people who were unable or unwilling to self-inject). These administration costs were determined to be 100.00 pounds sterling and 6.00 pounds sterling for LMWH and 83.00 pounds sterling and 6.00 pounds sterling for fondaparinux after hip or knee replacement, respectively.

The base-case analysis estimated that at 220 mg dabigatran etexilate was less costly and more effective than LMWH for both hip and knee replacement surgery. At the lower dose of 150 mg, dabigatran etexilate was less costly and more effective than LMWH for hip replacement surgery, but was more costly and less effective than LMWH for knee replacement surgery. In univariate sensitivity analyses none of the parameters were associated with a significant difference in the base-case results.

The economic evaluation estimated that at both doses dabigatran etexilate is less costly but also less effective than fondaparinux after hip replacement (incremental cost-effectiveness ratios [ICERs] were in the 'southwest' quadrant of the cost-effectiveness plane). After knee replacement, dabigatran etexilate at both doses was dominated by fondaparinux (that is, it was more costly and less effective than fondaparinux). In sensitivity analysis, increasing the relative risk of VTE for fondaparinux was associated with dabigatran etexilate dominating for hip replacement and being less costly, but being less effective in knee replacement.

Probabilistic sensitivity analysis and cost-effectiveness acceptability curves suggested probabilities of dabigatran etexilate being cost effective compared with LMWH (at a willingness-to-pay threshold range of 20,000 pounds sterling per additional Quality Adjusted Life Years Saved [QALY] gained) of 99% for the 220-mg dose after hip replacement, 82% for the 220-mg dose after knee replacement, 76% for the 150-mg dose after hip replacement, and 38% for the 150-mg dose after knee replacement). The corresponding results for dabigatran compared with fondaparinux were 40% for the 220-mg dose and 32% for the 150-mg dose after hip replacement, and zero for both doses after knee replacement).

Following a request for clarification from the Evidence Review Group (ERG), the manufacturer provided cost-effectiveness analyses with inputs from meta-analysis which included data from the RE-MOBILIZE trial. The revised economic evaluation estimated that dabigatran etexilate was dominated by LMWH (that is, it was more costly and less effective than LMWH) for knee replacement at both 220-mg and 150-mg doses.

The ERG commented that the mixed-treatment comparison did not provide indirect comparisons of fondaparinux and dabigatran etexilate, making it difficult to reach conclusions about their relative efficacy and safety. The ERG also noted that the outcome assessed in the mixed-treatment comparison was deep vein thrombosis (DVT) (not the composite primary outcome of the dabigatran etexilate trials). It was also unclear how the trial data had been used to derive the mixed-treatment comparison of DVT outcome. The ERG suggested that results of the manufacturer's mixed-treatment comparison should be considered with caution.

The Committee considered the results of the economic evaluation and noted that because of the closeness of all the effectiveness and cost data, the ICERs were very sensitive to changes in assumptions. At the 220-mg once-daily dose

dabigatran etexilate was less costly and more effective than LMWH for both hip and knee replacement. At the lower dose of 150 mg, dabigatran etexilate dominated LMWH for hip replacement, but was dominated by LMWH for knee replacement. It noted that results were not very sensitive to reduced drug acquisition costs reflecting the reduced purchase price available to some NHS trusts.

The Committee noted that in the base-case modelling dabigatran etexilate at either dose was less costly and less effective than fondaparinux in hip replacement and more costly and less effective than fondaparinux in knee replacement. However, the Committee was mindful of the small differences between interventions and noted the sensitivity of the model results to changes in clinical effectiveness inputs.

Furthermore, the Committee considered that the model had not attempted to incorporate the utility benefits (in the form of disutility avoided) of oral administration over injection, and that the potential benefit of greater adherence with oral as opposed to subcutaneous treatment had been modelled conservatively.

Overall, taking into account that the cost and effectiveness data of dabigatran etexilate are similar to those of LMWH and fondaparinux, and that some benefits of the availability of an oral formulation had not been captured in the modelling, the Committee concluded that dabigatran etexilate was as cost-effective a use of National Health Service (NHS) resources as LMWH or fondaparinux.

Refer to Sections 3 and 4 of the original guideline document for more information on cost-effectiveness.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Dabigatran etexilate, within its marketing authorisation, is recommended as an option for the primary prevention of venous thromboembolic events in adults who have undergone elective total hip replacement surgery or elective total knee replacement surgery.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of dabigatran etexilate for the prevention of venous thromboembolism after hip or knee replacement surgery

POTENTIAL HARMS

According to data reported in the summary of product characteristics (SPC), around one in seven people undergoing hip or knee surgery and treated with dabigatran etexilate experienced a bleeding event (13.8% of those receiving daily doses of 220 mg or 150 mg). Major bleeds were common and were experienced by 1.8% and 1.3% of people treated with 220 mg or 150 mg dabigatran etexilate, respectively. Other common adverse effects (those occurring in at least 1%, but less than 10% of patients) include gastrointestinal haemorrhage, wound secretion, anaemia, and haematoma.

For full details of side effects and contraindications, see the SPC.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of

their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

- The Healthcare Commission assesses the performance of National Health Service (NHS) organizations in meeting core and developmental standards set by the Department of Health in "Standards for better health" issued in July 2004. The Secretary of State has directed that the NHS provides funding and resources for medicines and treatments that have been recommended by the National Institute for Health and Clinical Excellence (NICE) technology appraisals normally within 3 months from the date that NICE publishes the guidance. Core standard C5 states that healthcare organisations should ensure they conform to NICE technology appraisals.
- "Healthcare Standards for Wales" was issued by the Welsh Assembly Government in May 2005 and provides a framework both for self-assessment by healthcare organisations and for external review and investigation by Healthcare Inspectorate Wales. Standard 12a requires healthcare organisations to ensure that patients and service users are provided with effective treatment and care that conforms to NICE technology appraisal guidance. The Assembly Minister for Health and Social Services issued a Direction in October 2003 which requires Local Health Boards and NHS Trusts to make funding available to enable the implementation of NICE technology appraisal guidance, normally within 3 months.
- NICE has developed tools to help organisations implement this guidance (listed below). These are available on the NICE website (www.nice.org.uk//TA157) (see also the "Availability of Companion Documents" field).
    - A costing statement explaining the resource impact of this guidance
    - Audit support for monitoring local practice

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Patient Resources
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Dabigatran etexilate for the prevention of venous thromboembolism after hip or knee replacement surgery in adults. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Sep. 26 p. (Technology appraisal guidance; no. 157).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2008 Sep

GUIDELINE DEVELOPER(S)

National Institute for Health and Clinical Excellence (NICE) - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Appraisal Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Professor David Barnett, Professor of Clinical Pharmacology, University of Leicester; Dr David W Black, Director of Public Health, Chesterfield PCT; Mr Brian Buckley, Chairman, Incontact; Dr Carol Campbell, Senior Lecturer, University of Teesside; Professor Mike Campbell, Professor of Medical Statistics, University of Sheffield; Professor David Chadwick, Professor of Neurology, University of Liverpool; Dr Christine Davey, Senior Researcher, North Yorkshire Alliance R & D Unit; Dr Mike Davies, Consultant Physician, Manchester Royal Infirmary; Mr Richard Devereaux-Phillips, Public Affairs Manager, Medtronic Ltd; Dr Rachel A Elliott, Lord Trent Professor of Medicines and Health, The University of Nottingham; Mrs Eleanor Grey, Lay member; Dr Dyfrig Hughes, Senior Research Fellow in Pharmacoeconomics, Centre for the Economics of Health and Policy in Health, University of Wales; Dr Peter Jackson, Clinical Pharmacologist, the University of Sheffield; Ms Rachel Lewis, Nurse Advisor to the Department of Health; Dr Damien Longson, Consultant in Liaison Psychiatry, North Manchester General Hospital; Professor Jonathan Michaels, Professor of Vascular Surgery,

University of Sheffield; Dr Eugene Milne, Deputy Medical Director, North East Strategic Health Authority; Dr Simon Mitchell, Consultant Neonatal Paediatrician, St Mary's Hospital, Manchester; Dr Katherine Payne, Health Economics Research Fellow, The University of Manchester; Dr Philip Rutledge, Consultant in Medicines Management, NHS Lothian; Mr Miles Scott, Chief Executive, Bradford Teaching Hospitals NHS Foundation Trust; Dr Surinder Sethi, Consultant in Public Health Medicine, North West Specialised Services Commissioning Team; Professor Andrew Stevens, Chair of Appraisal Committee C; Dr Cathryn Thomas, Senior Lecturer, Department of Primary Care & General Practice, University of Birmingham; Dr William Turner, Consultant Urologist, Addenbrooke's Hospital

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Dabigatran etexilate for the prevention of venous thromboembolism after hip or knee replacement surgery in adults. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Sep. 2 p. (Technology appraisal 157). Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Dabigatran etexilate for the prevention of venous thromboembolism after hip or knee replacement surgery in adults. Costing statement. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Sep. 2 p. (Technology appraisal 157). Available in Portable Document Format (PDF) from the NICE Web site.
- Dabigatran etexilate for the prevention of venous thromboembolism after hip or knee replacement surgery in adults. Audit support. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008. 4 p. (Technology appraisal 157). Available in Portable Document Format (PDF) from the NICE Web site.
- Dabigatran etexilate for the prevention of venous thromboembolism in patients undergoing elective hip and knee surgery: a single technology appraisal. Evidence review group report. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 May 9. 150 p. (Technology appraisal 157). Available in Portable Document Format (PDF) from the NICE Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N1688. 11 Strand, London, WC2N 5HR.

PATIENT RESOURCES

The following is available:

- Dabigatran etexilate to reduce the risk of venous thromboembolism after hip or knee replacement surgery. Understanding NICE guidance - Information for people who use NHS services. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Sep. 4 p. (Technology appraisal 157).

Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the NHS Response Line 0870 1555 455. ref: N1689. 11 Strand, London, WC2N 5HR.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI Institute on January 14, 2008.

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